STATE OF MINNESOTA DISTRICT COURT

COUNTY OF RAMSEY SECOND JUDICIAL DISTRICT

- -

The State of Minnesota,
by Hubert H. Humphrey, III,
its attorney general,
and
Blue Cross and Blue Shield
of Minnesota,

Plaintiffs,

vs. File No. C1-94-8565

Philip Morris Incorporated, R.J.
Reynolds Tobacco Company, Brown
& Williamson Tobacco Corporation,
B.A.T. Industries P.L.C., Lorillard
Tobacco Company, The American
Tobacco Company, Liggett Group, Inc.,
The Council for Tobacco Research-U.S.A.,
Inc., and The Tobacco Institute, Inc.,

Defendants.

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DEPOSITION OF DAVID G. BENDITT, M.D.

Volume II, Pages 201 - 257

(The following is the continued Deposition of DAVID G. BENDITT, M.D., taken pursuant to Notice of Taking Deposition, at the offices of Dorsey & Whitney, Attorneys at Law, 220 South Sixth Street, Minneapolis, Minnesota, on September 16, 1997, commencing at approximately 9:07 o'clock a.m.)

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E X A M I N A T I O N I N D E X

E X H I B I T I N D E X

P R O C E E D I N G S

(Plaintiffs' Deposition Exhibit 3807 was marked for identification.)

(Witness previously sworn.)

DAVID G. BENDITT, M.D.,

called as a witness, being previously sworn, was examined and testified as follows:

ADVERSE EXAMINATION (cont'd.)

BY MS. FLYNN PETERSON:

Q. Dr. Benditt, we are going to proceed with your deposition. You understand that you are under oath from yesterday?

A. Correct.

Q. When we concluded last evening, I provided you with a copy of Dr. Graham's report. When we discussed it earlier in the day, you asked for an opportunity to review the report. Have you had an opportunity to do that, sir?

A. Yes, I did.

Q. I'd like to refer you, then, to Dr. Kevin Graham's report in this litigation. Generally, as we begin to review the report, in reviewing it yourself last evening, did you find any areas of disagreement with Dr. Graham?

A. No, I did not find anything that I thought was

important areas of disagreement. We may find some areas that we'll have minor disagreements on as we go through it, but overall I felt what he has offered us is a general review of cardiology as it applies to cardiac disease and, in that sense, it's a nice little primer.

Q. I'd like to refer you specifically to page 2, Dr. Benditt. On page 2, in the third paragraph, Dr. Graham sets forth a threefold approach that a physician, according to him, takes when a patient presents with an atherosclerotic clinical event. Do you agree with those approaches that are laid out in numbers one, two, and three, paragraph 3 of page 2?

A. Yes, I think that basically that's reasonable.

Q. Is that approach, in your opinion, consistent with accepted standards of medical practice?

A. Yes.

Q. On page 3 of Dr. Graham's report, under the section entitled coronary artery disease, Dr. Graham sets forth beginning in paragraph 2 the most common -- some of the most common presentations of coronary artery disease and sets forth initially stable angina. My question to you, Dr. Benditt, is: Do you agree with the diagnostic approach that is suggested by Dr. Graham with respect to a patient who presents

with stable angina?

A. Yes.

Q. Are the tests he suggests reasonably necessary from a medical standpoint for a patient who presents with stable angina?

A. Yes.

Q. And would the performance of those tests be in accord with accepted standards of medical practice?

A. I believe so.

Q. I will ask you the same questions with respect to the next paragraph. When a patient presents with unstable angina is the subject of that particular paragraph, is it not?

A. Yes, it is.

Q. And Dr. Graham suggests a diagnostic treatment approach for such a patient. Do you believe the approach as suggested by Dr. Graham is consistent with accepted standards of medical practice?

A. Yes, they are.

Q. And are the diagnostic and therapeutic tests that he recommends reasonably necessary for a patient who presents with unstable angina?

A. Yes, they are, but here, as in the previous paragraph, one wouldn't necessarily have to do all of the items that he has cited.

Q. Would it depend on the individual patient?
A. Correct.
Q. And for individual patients who present with either stable or unstable angina, in your experience and expertise, would those tests in particular patients be reasonably necessary?
A. Yes. In a selected way. I mean it may be that some people will have all of this done and others will have maybe only one of these items done. With that caveat, the answer is yes.
Q. Then going on to page 4. Do you agree with Dr. Graham in paragraph 1 that patients that present with acute myocardial infarction are medical emergencies?
A. Yes.
Q. Do you agree that a reasonably -- reasonably necessary medical procedure for such a patient if they present within six to 12 hours may be the use of thrombolytic agents or TPA?
A. There is, I think, some ongoing disagreement about that. The use of Heparin may be comparably effective. TPA that he has cited here is commonly used at the Minneapolis Heart Institute, it's my understanding, and it's perhaps the most expensive approach, so I would think that he's given TPA as an example but the term "thrombolysis" might include

other things such as streptokinase, which are far less expensive. But again with those caveats, I think he's basically laid out a reasonable plan.

Q. Do you agree that for a patient who presents with acute myocardial infarction it may be medically necessary for that patient to proceed to angioplasty?

A. Yes.

Q. Do you agree with Dr. Graham's opinion that for patients, after thrombolysis, that they may need additional stress testing or angiography?

A. Yes.

Q. Do you also agree that for these patients there is a high percentage that receive interventional cardiac procedures such as coronary bypass surgery?

A. Yes. I'm not sure what a "high percentage" means, but I think if we use it in a very general sense I think the response would be once again yes. It should be pointed out that I believe it's very much medical-center related and that the tendency might be a lot higher, say, at the Minneapolis Heart Institute than at other medical centers around the community.

Q. What tendency?

A. The tendency to undertake conventional cardiac procedures.

Q. What is the basis for your opinion?
A. Well their reputation in the community is to take a high level of invasive procedures because it generates a lot of income.
Q. Is that the reason they undertake the procedures for the patients?
A. Well I think it would probably be unfair for me to say that categorically, but I think the implication is that there may be many different ways to handle the same patients and that there is a lot of concern about the appropriate use of interventional procedures, and there is a lot of debate about difference of opinion and it might be reasonable to say their opinion, from my perspective, which could be incorrect, is that there is a great need to do interventional procedures whereas I think others in the community would probably find that that's not the case.
Q. And who --
A. These are areas of reasonable medical differences.
Q. And who would those others in the community be?
A. Well I think you will find at the university, for example, the level of interventional procedures in acute myocardial infarction is much lower than it

would be at Minneapolis Heart Institute. I think that's also true at Park Nicollet Clinic in St. Louis Park where I've had some minor experience. I think that's also true at St. Cloud Hospital where I've had a lot of experience, even though they have an excellent interventional cardiology team.

Q. Are you aware of any statistics relative to the level of interventional cardiology at the institutions you have mentioned, at Minneapolis Cardiology, U of M, Park Nicollet or St. Cloud?

A. No, not specific statistics. What I'm giving you is a general impression, but I suspect those statistics could be made available if you are really interested in knowing them.

Q. Is it your opinion there are patients who undergo interventional cardiology treatment at Minneapolis Clinic where it's not reasonably medically necessary?

A. I wouldn't go so far as to say that. I think there is a difference of opinion in the approach to care of patients and all of those may be well within the realm of reasonable practice.

Q. Do you agree with Dr. Graham's opinion that patients who present with completed myocardial infarction as their initial presentation or after

failed thrombolysis often develop congestive heart failure?

A. I would have felt happier with that paragraph if he had been more specific. I think the term "often develop congestive heart failure" is nebulous in many respects. He doesn't tell us what "often" means and the term "develop" goes far into the future. Are we talking about three months, six months, 10 years? That particular sentence is true in a primer sense. I mean, as I said, this is a primer of cardiology. This particular paragraph would be completely decimated if it were presented in a peer-review article because it's extremely nebulous as to what it really means. It's certainly true that many people with ischemic heart disease develop congestive heart failure but some of those people develop congestive heart failure instantly, within days of their heart attacks, and others maybe 30 years later. So I think this statement is true but insufficiently precise to be very meaningful.

Q. What has been your experience in the percentage of patients you treated with a completed myocardial infarction that develop congestive heart failure?

A. Over what period of time I guess is really --

Q. What period of time would be easier for you to

estimate that?

A. My practice has only extended 20 years so I can't discuss periods longer than that and I think it would probably be -- I would probably say that within a five- to 10-year period patients with completed myocardial infarctions in my estimation, probably about 20 to 30 percent of them would develop symptoms of chronic congestive heart failure. It does depend on the severity of the initial infarction, of course.

Q. Has it been your experience that patients with a completed myocardial infarction are at high risk for arrhythmias?

A. Yes.

Q. Do you know what percentage of that risk in your particular practice?

A. Again it depends on the severity of the myocardial infarction, but there are very precise statistics available on this topic. If one has different degrees of myocardial dysfunction, one has increasing or varying degrees of risk.

Q. What if you have scarring of the left ventricle, does that help you delineate that more specifically?

A. No, because scarring of the left ventricle is basically of a sine qua non of a completed myocardial infarction. In other words, scarring occurs because

of damage to the heart muscle and it might be just a minute, small area or it might be extremely extensive. Scarring also occurs as a result of non-ischemic heart disease, wear and tear from hypertension, cardiomyopathies, et cetera, so it's neither a very helpful or specific finding.

Q. If you use it in reference to those individuals who have had a myocardial infarction significant enough to cause that permanent damage to the left ventricle, using those parameters, does that help you in any way to better estimate the relative risk or, excuse me, the risk of arrhythmic sudden cardiac death?

A. No, it really doesn't. The risk of arrhythmic sudden cardiac death is -- can be characterized by a number of measures of myocardial function which are available in community practice, and perhaps the one that's most effective as an assessment is what we call the ejection fraction. Ejection fraction is a measure of the heart's pumping performance and as one's ejection fraction, which is normally in the 55 to 65 percent range, falls, then the increase -- then there is an increased risk of potentially lethal arrhythmias, and that characterization is fairly well established.

Q. With respect to patients who following a myocardial infarction do develop an arrhythmia, what kind of medical therapy do they require?

A. It may vary from nothing to the implantation of a cardioversion wall defibrillator in conjunction perhaps with certain antiarrhythmic drugs. On rare occasion these days, cardiac surgery is necessary and on rare occasion so-called transcatheter ablation procedures are necessary, but the vast majority of patients probably receive no direct antiarrhythmic drug therapy because it's not considered necessary but they do, of course, receive ongoing therapy for their underlying heart disease.

Q. Which would include what?

A. Usually these days would include nitrates of various forms, nitroglycerin or long-acting nitrates, ACE inhibitors, A-C-E inhibitors, beta blockers very commonly, occasionally calcium channel blockers, aspirin. Those are probably the four main treatments.

Q. Does a patient such as that require medical monitoring on any regular basis?

A. That certainly is advisable, yes.

Q. On what basis?

A. The frequency of monitoring would depend, of

course, on the severity of the patient's symptoms and the severity of the heart disease, but I think you could probably say that typically two or three times a year they would be seen by a cardiologist and/or internist.

Q. If we proceed to the final paragraph on page 4 that deals with sudden cardiac death, Dr. Graham used the same percentage you did, 30 percent with acute myocardial infarction can have sudden cardiac death.

A. I think if you take that in global terms, what he is really referring to is the occurrence of death prior to reaching medical facilities. That means that what he is basically saying is that a certain percentage of patients who have heart attacks at work, at home or on the street are never admitted to hospitals because they don't survive.

Q. So is the figure that you gave us of 30 percent for those people who are hospitalized and survive the myocardial infarction, --

A. Correct.

Q. -- they have an additional 30 percent risk of dying from arrhythmia after that?

A. I didn't use the term 30 percent. I think the only time I used percentage terms was in conjunction with your question related to heart failure. The

percentage terms that relate to people who survive myocardial infarctions and then are dismissed from hospital and followed, the frequency of sudden death in that group depends on the ejection fraction, and the lower the ejection fraction the higher the incidence of sudden death. There are other factors involved, too, but I think that's probably sufficient for this point in time.

What he is alluding to here is sudden cardiac death, and sudden cardiac death might occur in a patient who has had a previous myocardial infarction but sometimes it's, and often -- I think he is trying to make this point -- is the presenting feature of -- of an illness, and in that sense these patients never get to the hospital, are never admitted or never undergo all these tests and what have you.

And if one was being cynical, which I hope nobody would be, although it's commonly thought in some medical-insurance schemes that this is the global plan, is that if patients never get to the hospital the cost of caring for them is negligible. That, of course, is entirely contrary to the medical ethical approach to taking care of patients, but nevertheless there is a certain percentage of patients that we are trying to prevent from dying

before they reach medical care. And one of the reasons we find this a particularly disconcerting concept is because our particular research in cardiopulmonary resuscitation is addressing exactly this 30 percent of patients plus others, and the -- both the health insurance community as well as the government have been extremely unhelpful in supporting research into this area, almost to the point where one could argue they don't want these patients to reach a hospital.

Q. In your experience, Dr. Benditt, what percentage of patients who survive myocardial infarction develop some type of anoxic encephalopathy?

A. That's a very difficult question. I would say that in my experience probably fewer than 5 percent, probably fewer than even 1 percent.

Q. In your practice at the university today, do you deal with patients with acute myocardial infarction and treat them following that myocardial infarction?

A. Yes, we do, although I would concede we don't see nearly the volumes of patients that Dr. Graham's group had seen.

Q. Would you agree that if a patient experiences a myocardial infarction, that angiography may be an appropriate testing mechanism for them?

A. Yes.
Q. You have had your own patients undergo those types of procedures after myocardial infarction?
A. I have.
Q. And the purpose of that is to determine whether additional therapy or treatment may help that patient?
A. Correct.
Q. It also helps you quantify the degree of damage done by the myocardial infarction?
A. It does. There may be, incidentally, if I can continue the response to that question, other non-invasive ways to get similar information.
Q. For some percentage of patients who present with myocardial infarction, is it necessary for those patients to go on to cardiac transplantation?
A. It's a rare event if that occurs when you consider the large number of patients who undergo myocardial infarctions each year. The total, just envisioning the Twin Cities community, which I suspect represents thousands of patients, the total, sum total of cardiac transplants that's been undertaken in the Twin Cities community, adding the university experience and the Minneapolis Heart Institute experience, which I think are the major

players in the Twin Cities, represents no more than 650 to 700 heart transplants in the last 10 to 15 years. When you think about the number of myocardial infarctions that go on annually, which is in the thousands, you can come to the conclusion that heart transplantation is not very common and treatment for these patients extremely rare.

Furthermore, of the patients who get heart transplants, I would venture to guess that more than half of them have never had myocardial infarctions and that the majority, probably 60 percent, represent various forms of cardiomyopathy that may be non-ischemic in origin. So I would say heart transplantation does not play an important role in this discussion.

Q. With respect to patients who go on to develop congestive heart failure, do you agree that those patients require recurrent hospitalizations?

A. They have a very high tendency to hospitalization cost, yes.

Q. Do you agree with Dr. Graham that congestive heart failure is now the most common reason for admission to American hospitals?

A. Does he say that?

Q. Page 6, paragraph number 4.

A. Yes, he does say that.

I wouldn't argue with him because he may be closer to the subject being an epidemiologist than I. Nevertheless, I guess I'm a little surprised with that statement given the large number of reasons that people are admitted to hospitals, including varieties of tests and what have you. If he insisted that that was correct, I wouldn't argue with him, but I would say I would have put it it may be the most common reason for cardiovascular admissions to American hospitals.

Q. Do you know?

A. I'm guessing.

Q. Then referring you to page 7, under long-term treatments, Dr. Graham has set forth four targets for therapy. Do you agree with those targets of therapy as being reasonable medical alternatives and long-term treatments for patients who have been stabilized after a coronary artery disease has been diagnosed?

A. I think these are the principal targets for therapy, yes.

Q. Do you agree with Dr. Graham that smoking cessation is the largest statistical risk factor for reduction that can be accomplished in one year's time

for both primary and secondhand smoke?
A. That's my understanding.
Q. And do you agree the risk for myocardial infarction is decreased 50 percent in one year's time in a patient who ceases smoking?
A. That I believe is a number that's commonly stated, yes.
Q. Do you agree with that number?
A. I don't have any reason to disagree with it. I'm not as familiar with the range of that number as other -- as Dr. Graham might be, but I wouldn't quibble with that number.
Q. And just referring you to page 8 of this report, in paragraph 2 on page 8, do you agree with Dr. Graham that patients who present with symptomatic atherosclerosis need enormous amounts of health care both on an acute and chronic basis?
A. Yes, as a general rule I think that symptomatic cardiovascular disease for atherosclerosis is a very health-care intensive business.
Q. And referring you to the final paragraph of Dr. Graham's opinion, do you agree with Dr. Graham the services provided --
(Interruption by the reporter.)
Q. Do you agree with Dr. Graham's opinion, based on

your own experience, Dr. Benditt, that the services provided to patients in programs covered by the state of Minnesota or Blue Cross/Blue Shield of Minnesota are medically necessary for those patients?

A. Well I think I agree with the sense of what he is saying but in fact the way he has put it is incorrect.

Q. In what way?

A. Well, it was unknown to me that either the state of Minnesota through the Medicaid program, apart from the physicians that might be employed by the state, or Blue Cross/Blue Shield, other than physicians that they might directly employ, provide any medically necessary treatment.

My understanding is that the state and Blue Cross/Blue Shield are insurance firms and the services they provide are basically to ensure patients and provide payment for medical services that are delivered by practitioners who are licensed to do so. So in that sense, the sentence is misleading. Furthermore, the -- what isn't said in this sentence is also misleading, and that is that we don't know what services are not provided by these agencies or covered by these agencies that may be medically necessary, and I think that's an equally

important aspect of the insurance business.

Q. Has it been your experience, Dr. Benditt, that the fees paid by Blue Cross/Blue Shield of Minnesota are on par with customary reimbursement in the Minnesota medical market?

MR. BORMAN: I'll object to that question on lack of foundation.

Go ahead, doctor.

A. Actually, this is an interesting statement. Frankly, I believe that these folks set the fees and that there is really no argument as to the nature of the fees, so the concept of customary reimbursement is really a nonsensical one. The concept that most physicians see in terms of the way Blue Cross/Blue Shield and other insurers handle medical care payments is perhaps analogous to my going in to buy a Cadillac and offering them $5,000, take it or leave it, I get the car. So the customary reimbursement issue is really I think a -- a non-issue here. It's -- There is no such thing. It's basically a take-it-or-leave-it payment. In terms of state of Minnesota, they may pay less than Blue Cross/Blue Shield. I'm not familiar with that. I don't pay a lot of attention to these things because essentially, as I say, we get paid what they are willing to pay

and we have to take care of the patients whether they are willing to pay for it or not, and as you are well aware, both the state as well as insurers frequently fail to insure many elements of our society, particularly children, and in those cases we end up taking care of those individuals despite absence of payments of any customary fees, whatever that means, by these or other agencies. So, this particular sentence is just sort of a meaningless statement.

Q. I'd now like to show you what has been marked as Plaintiffs' Exhibit 3807, and as we did yesterday, I will just give you an opportunity to review that document. For the record, I will identify it as American Heart Association publication "Children and Smoking: A Message to Parents."

Does it appear I've correctly identified Exhibit 3807, Dr. Benditt?

A. Yes, you have.

Q. Take an opportunity to review it. I will ask you some questions regarding that document.

A. Yes, please go ahead.

Q. Are you familiar with Plaintiffs' Exhibit 3807?

A. I have seen it, yes.

Q. That was one of the -- That is one of the American Heart Association publications that we were

provided by the Minnesota affiliate. Had you been familiar with your work through the Minnesota affiliate of the American Heart Association?

A. I was familiar with this subsequent to that work, but nevertheless, I've seen this publication.

Q. Does the document indicate what years it has been in publication by the American Heart Association?

A. Yes. It's been in publication since 1987.

Q. And I believe we established yesterday that your work with the American Heart Association on the board of directors was from 1984 to 1994; correct?

A. That's correct, but nevertheless I don't recall having seen it in those years. I may have. I've certainly seen it subsequently.

Q. Do you agree with Exhibit 3807 that smoking is a serious health problem in the United States?

A. Yes.

Q. Do you agree with the surgeon general's statement as reflected in this document that the surgeon general has called cigarette smoking the single most preventable cause of death?

A. The surgeon general may well have said that.

Q. Do you agree with the statement in this Exhibit 3807 that heart and blood vessel disease claim 42

percent of all deaths attributed to cigarette smoking per year?

A. Can you point out where that's --

Q. I'm just beginning at the very top and going forward, so we are still on page 1. It would be in the second paragraph.

MR. BORMAN: I'll object to that question for lack of foundation, but go ahead, doctor.

A. Well that certainly is what it says and I wouldn't have any reason do dispute that.

Q. Is that consistent with your experience as a cardiologist practicing for 20 years?

A. Yes.

Q. Dr. Benditt, do you have children who are patients of yours as well as adults in your practice?

A. I do.

Q. What is your opinion as a physician with respect to children and smoking?

MR. BORMAN: Object to the form of the question.

A. I endeavor to dissuade people from smoking at all ages.

Q. And why is that?

A. Well because my basic concern is that I believe that in terms of habit, that it's not a healthy habit

in terms of my concerns with both lung and cardiovascular disease, and I think smoking is well recognized as a risk factor, especially for cardiovascular disease, and my role in trying to prevent cardiovascular disease from being aggravated requires -- is consistent with that advice.

Q. From an epidemiological standpoint, Dr. Benditt, would you agree that smoking has been determined to be a cause of coronary heart disease?

A. I think from an epidemiologic standpoint, smoking has been determined to be an important risk factor.

Q. So you disagree with my statement?

A. Yes.

Q. Would you agree that evidence exists to establish to a reasonable degree of medical certainty that smoking is a cause in multiple correlations with coronary heart disease?

MR. BORMAN: I'll object to the form of the question.

A. I think that in a nutshell, the evidence that we went through in considerable detail yesterday and is out in the literature clearly points to smoking as a risk factor for coronary artery disease and other vascular diseases. The term of "cause" is something

that we went through in considerable detail yesterday and I think that the evidence is not sufficiently unequivocal in that regard.

Q. Is that from an epidemiological standpoint as well?

A. Well I think that it's impossible from an epidemiologic standpoint in multifactorial conditions to make statements related to the cause in groups or individuals. I think the epidemiologic data provides us insight, important insight into identifying risk factors which may or may not turn out to be the cause but require further scientific study to find out.

Q. Dr. Benditt, then you disagree that from an epidemiological standpoint that smoking has been determined to be a cause of coronary heart disease?

A. That's correct.

Q. Would you agree that substantial evidence exists to establish to a reasonable degree of medical certainty in multiple studies that smoking is a substantial factor in bringing about coronary heart disease?

MR. BORMAN: Again object to form.

Go ahead, doctor.

A. A substantial factor --

(Discussion off the record.)

A. A substantial factor is defined as -- as what? I guess just as we have talked yesterday about major, I think we got into a lot of discussion about that term. Just as I had some disagreement with Dr. Graham about the term "often," I think the term "substantial" represents another one of these qualitative things that are very important in public health education pieces such as this, and I believe we all try to convince folks by using terms like that, that when we come down to identifying in real scientific terms what the relationships are, we have to be more specific.

Q. Would you agree that evidence exists to a reasonable degree of medical certainty that it is more likely true than not true that smoking is a cause of coronary heart disease?

MR. BORMAN: Same objection.

Go ahead, doctor.

A. Well I think it more likely true than not true. I think one could say that it may be more likely true, but what does that really mean? Is that 51 percent versus 49 percent? I don't know. I think that my view of the subject is that it's more likely true only in the sense that we have weeded out other risk factors such as oxygen in the air, for example,

by doing very important epidemiologic study. So we are in the ball park, perhaps, but we don't have any specifics at this stage that allow us to say any more than that.

Q. In your opinion there are no specifics available to physicians and scientists to determine whether it is more likely true than not true that cigarette smoking causes coronary heart disease?

A. I didn't say that.

Q. I'm just trying to clarify your opinion, doctor.

A. My opinion is that we are -- we have a series of risk factors which have been clearly identified in epidemiologic studies, and the role those risk factors play, either alone or together in the cause of the disease, is something that needs -- that we need to do more research to find out, and that research is something that probably could get answers to the questions if appropriately supported.

Q. Would you expect that the tobacco industry carries out such research as they continue to market their product?

A. I have no idea whether they do that or not.

Q. Would you consider it to be appropriate?

A. I consider it appropriate for any organization

that markets a product commercially to learn as much as they can about the various implications of the product, yes.

Q. Dr. Benditt, do you know of any authoritative body in the medical or scientific community that disagrees with the conclusion that smoking is a major and independent cause for the development of coronary heart disease?

A. Yes, I do.

Q. And who is that?

A. First four references in my expert testimony.

Q. And each of those four references in your opinion disagree that smoking is a major independent cause for the development of coronary heart disease?

A. Each of those papers states precisely that smoking is a risk factor and certainly two of them state that there is a clear-cut distinction to be made between risk factor and cause. I think if we want to look specifically, pull one out, you look at the paper by Levy and Braunwald's textbook on the very bottom of the first page. It's not -- It's reference 2 in my --

Q. Are you finished answering the question?

A. Yes.

Q. Referring you to reference 1, we discussed

yesterday those authors conclude that causality can only be proven by intervention trials and you disagreed with that yesterday. Do you still disagree with that?

A. Depends on whether it's an epidemiologic study or not. I mean, an intervention trial in the animal laboratory might be quite effective. I think we were talking about epidemiologic studies yesterday.

Q. I'm referring to your first reference.

A. And --

Q. Did you agree with the statement given by these authors, Hopkins and Williams, in your first reference that causality can only be proven by intervention trials?

A. In a positive sense, yes.

Q. Do you agree with these authors that cigarette smoking and more recently high blood pressure are accepted by most experts to be causal for coronary heart disease because of results from intervention trials?

A. I can't say what most experts believe and I'm not sure those authors can say that, but that's what they have stated.

Q. Do you agree with that?

A. I don't necessarily agree with that, no, because

the intervention trials that they are talking about are not the intervention trials that I deem necessary to make a statement about cause. These folks are talking about epidemiologic studies, and I'm not sure exactly what specific intervention trials they are referring to. We would have to look at each one of them to discuss that as to whether I would agree with it with respect to each study. But in a general sense, the intervention trials have not provided a basis for direct cause.

Q. And do you understand in holding that opinion, Dr. Benditt, you are in the minority view in the medical and scientific community?

A. I don't believe that's true.

Q. When you refer to Levy's article and the Braunwald text, you disagree with their conclusion that overwhelming evidence supports a strong and definite relationship between cigarette smoking and coronary artery disease?

A. I didn't disagree with that.

Q. Have multiple large and well-respected study such as the Framingham study we discussed yesterday and the Mr. Fit study and the Pooling Project show smoking causes coronary heart disease?

A. No.

Q. Have there been several large and well-respected studies including the Framingham study, the Mr. Fit study and the Pooling Project that have shown that it can be reliably predicted that if smoking is stopped or decreased that the incidence of disease decreases?
A. The incidence of manifestation of the disease decreases, I don't think there is evidence that the disease -- Sorry. I don't think there is evidence that the disease decreases.
Q. Would you agree that smoking acts synergistically with other major risk factors to greatly increase the risk for coronary heart disease?
A. I believe that's correct, yes.
Q. Would you agree that the longer a person smokes, the greater risk of coronary heart disease?
A. I believe that's correct.
Q. Do you agree that in an individual with multiple risk factors for coronary heart disease, that if they stop -- stop smoking, the risk of disease for them will decrease?
A. The risk of manifestation of disease will decrease, but we don't have any evidence that's unequivocal to suggest that the disease itself regresses, --
Q. What do you --

A. -- at least at a rate that we can measure.
Q. What man --
What do you mean by "manifestations"?
A. As you pointed out earlier and we discussed several times, certain manifestations of cardiovascular disease such as angina pectoris and acute myocardial infarction appear to be of increased frequency in individuals who smoke and decreased frequency in individuals following smoking cessation. Those are manifestations of cardiovascular disease, particularly in the case of our discussion of atheromatous disease. We know from certain studies that other risk factors, when drawn, can be associated with physical regression of disease, and although I think that there is still debate about this there seems to be some evidence with respect to reducing lipids, cholesterol, for example, and angio -- sequential angiographic studies suggests regression of coronary disease. That's not been universally accepted but at least there is some evidence in that direction. I'm unaware of any evidence that show the same thing in smoking cessation, although the frequency of the manifestations of disease may go down.
Q. And those manifestations would include the

subsequent development of myocardial infarction?
A. Correct.
Q. They would include increase in severity of atherosclerosis?
A. Don't know that.
Q. Would they include a decrease in angina or not?
A. We think so, yes.
Q. Any other manifestations specifically?
A. Claudication in peripheral vascular disease.
Q. Which would be a continuation of that process and ultimately leading to claudication?
A. Continuation of what process?
Q. The process of peripheral vascular disease that decreases circulation; correct?
A. Yes. I think we want to be very specific about the difference between the disease itself and its manifestations. We certainly know of people who have very severe disease with few manifestations, and other people who have very minimal disease, it seems, who have very severe manifestation, and this is part of medical practice and, frankly, it's inexplicable to many of us, but nevertheless certainly occurs. So the disease process, the physical disease itself is one thing. Its manifestations can be affected by other factors such as hypertension, smoking, and

perhaps other medications even. We discussed some of these yesterday. So I think it's important to separate out the disease from the manifestations of the disease.

Q. But you would agree when an individual, no matter how long they smoked or how much they smoked, stopped smoking, that the manifestations of coronary disease do decrease?

A. On an epidemiologic basis, that's been shown, appears to be very convincing.

Q. And have you seen that in your own practice?

A. I can't say that I've ever measured it in my own practice. I follow that teaching in my practice and try to convince individuals, if they are smokers and they do have cardiovascular disease, to cut back or stop smoking. I haven't made it a practice of trying to measure the outcome such as epidemiologists might do.

Q. Have you made any observations within your own practice that lead you to confirm those findings of the epidemiologists?

A. No, I really haven't.

Q. Would you agree cardiovascular diseases are the leading causes of morbidity in this country?

A. That's a very difficult one to answer. I'd say

that one would need to focus that question more precisely. I have a hunch that probably automobile accidents are a more important cause of morbidity in this country.

Q. Do you have any specific studies that lead you to that conclusion?

A. There are a number of studies that show automobile accidents and accidents in general are the leading cause of death in young people, but I think the point I was trying to make by that statement is that the statement itself that you read is exceedingly general and really is not very helpful in the context of this discussion.

Q. Do you agree that cardiovascular disease is a significant cause of physical disability in our country?

A. It is.

Q. And you have seen that in your own practice?

A. I have.

Q. I was referring to the article that we mentioned yesterday that was reference 26 of yours, the seminars on respiratory medicine, and that article does state cardiovascular diseases are the leading cause of morbidity in this country, responsible for more than 1 of every 10 cases --

(Interruption by the reporter.)

Q. -- for well more than one of every 10 cases of dysfunctionally impaired health and disability within the working population.

Do you have any opinion as to whether that's true or not true?

A. No, I don't, and I rather suspect the authors were referring to morbidity related to diseases as opposed to morbidity related to accidents and other items, but I don't have any specific knowledge to that effect.

Q. Would you agree that cardiovascular diseases are the most important causes of mortality in the United States?

MR. BORMAN: I'll object to the form of the question.

A. I think that's still true.

Q. Also in the reference 26, looking at the -- the section on epidemiological studies, reference 195 is cited, which is -- appears to be one of the same references you have cited, which is the 1983 surgeon general's report.

A. Correct.

Q. And the authors of your reference number 26, Dr. Brockie, B-R-O-C-K-I-E, et al, indicate that the --

state as follows: As summarized in the surgeon general's report focusing on smoking and cardiovascular diseases, as well as in several additional such reports, tobacco cigarette smokers have a twofold or so increased incidence of coronary heart disease.

Would you agree with that based on your knowledge of the literature and your experience?

MR. BORMAN: I'll object to the question on lack of foundation.

A. Well that's what the surgeon general's report says, at least as I recollect it and as we discussed at some length yesterday. That would amount to a risk factor of 1.7, which is what we essentially discussed yesterday, so that all sort of fits together.

Q. And it goes on to say that individuals who are tobacco cigarette smokers have a 70 percent greater rate of death from coronary heart disease. Would you agree with that based on your knowledge of the literature and your experience?

MR. BORMAN: Same objection.

A. Based on what we have discussed yesterday, I think that number still is about 1.7.

Q. And then finally states that tobacco cigarette

smokers have up to a fourfold greater risk for sudden death than do nonsmokers. Would you agree with that based on your knowledge of the literature and your experience as a cardiologist?

MR. BORMAN: Same objection.

A. I can't say I'm aware of the fourfold, but it's certainly higher and I wouldn't argue with a number of that general order.

Q. You said yesterday that I believe you had reviewed the report of Dr. Samet, that was one of the reports you reviewed but did not have a copy of.

A. This is correct.

Q. Dr. Samet, in his report, talks about the criteria from an epidemiological standpoint to interpret causation. Do you recall that he dealt with that subject in his report?

MR. BORMAN: I'm going to object to the questions unless you allow him to have the report in front of him so he can read it himself. That will be a continuing objection, if I may.

MS. FLYNN PETERSON: I think I have been -- When I had something specific, I asked him whether he agrees with or disagrees with it, I've been showing him the report. Right now I'm just asking him if he recalls Dr. Samet addressing it. If he doesn't

recall, I'm certainly willing to give him time to review the report.

MR. BORMAN: Fair enough.

A. I really don't recall him providing those data.

Q. I don't know if you can read my copy, which has some writing and highlighting on it, but there is a section -- I should show you I do have the report of Dr. Samet.

A. Correct.

Q. And as you had indicated, this is something you had reviewed prior to your deposition in preparation for your opinions in this case?

A. Correct.

Q. Okay. And showing you on page 7, Dr. Samet addressed epidemiological evidence is interpreted for causality according to criteria to provide a guide as to the strength of the evidence. Do you see that?

A. I see that. He cites two references which we should probably look at, references 5 and 6.

Q. Did you look at those references when you reviewed his report?

A. I can't recall what references 5 and 6 are so we would have to perhaps take a look at those.

Q. Let me go forward with my question, see whether you still need to do that. What I'm further, and I

thought this would be an easier way to talk about since you reviewed this report, what I'm really interested in is something you talked about yesterday, is you did not recall at the time I asked you what the surgeon general's criteria was with respect to causation, and you said you would have to review that. I thought this would provide us a simpler method of getting at that as opposed to going through the various aspects of the book. If you can't do it without looking at those references, we can take time to do that.

What I wanted to ask you further, Dr. Benditt, is: As he goes forward here, Dr. Samet does, he talks about the 1964 report of the surgeon general. Do you see that?

A. Yes, I do.

Q. And he further states what those criteria were that were used in the 1964 surgeon general's report. Do you see that? Perhaps you want to read that paragraph.

A. He -- The paragraph --

MR. BORMAN: You may read whatever portions you want, doctor.

A. Yes, he lists four criteria, which include consistency, strength of association, specificity of

association and temporal relationship with the association.

Q. Having read that, does that refresh your recollection with respect to what causation -- how causation was defined in the attorney general -- excuse me -- the surgeon general's -- I keep doing that -- the surgeon general's report.

A. Yes, they -- I don't recall that specifically but I'm willing to accept that these are criteria that they set out. There is a familiarity to them.

Q. With respect to those criteria epidemiologically as it relates to cause, are those criteria that you are familiar with in your own practice?

A. I don't practice epidemiology so I don't -- I mean, I don't practice epidemiology in a professional sense so I don't keep those types of criteria in the front of my mind. I deal with individual patients and in the treatment of individual patients, unfortunately, we can't use sort of global criteria. We have to deal with individuals, so in that sense I don't make this a standard part of my day-to-day practice.

Q. Okay.

A. I'm willing to accept those criteria as having been stated in the surgeon general's statements in

1964 and we would have to examine the evidence that is brought to bear in regard to each of those criteria to ascertain whether there is sufficient evidence to demonstrate cause when what we are dealing with is a risk factor or some identified issue that's going to impact the disease.

Q. Are you willing to accept those are -- that definition of cause and those criteria are reasonably used by epidemiologists as a standard method of determining causality?

A. I can't say with certain knowledge what epidemiologists use as a standard for cause.

Q. You don't have any foundation with respect to that to express an opinion one way or the other?

A. That's correct.

Q. If you use those criteria, the strength of an association, the specificity of the association, the temporal relationship of the association and the coherence of the association, do you believe that cigarette smoking has been determined to be a cause of coronary heart disease?

A. No, for exactly the reasons we have discussed yesterday, and I could give you some examples if you like.

Q. You can go forward.

A. The temporal relationship of the association is unproven, for one thing.

Q. Why do you hold that opinion?

A. Because in order to demonstrate a temporal relationship between a chronic disease and the occurrence of smoking is, in my view, virtually impossible. It's not like you give a patient a bacterium and they develop pneumonia two days later. This is a temporal association that has not been proven, and I think, frankly, epidemiologists selecting that criteria are basically setting themselves up for failure.

To go on to specificity, specificity implies that in a normal population we wouldn't expect to see the disease. By "normal population," in this case I would say a nonsmoking population. But we do see atherosclerotic disease in a nonsmoking population, so the specificity criteria fails.

Again I think they set themselves up for failure if they demand those criteria. Nevertheless, if we are going to argue based on those criteria, two of them fail automatically in my estimation.

The coherence criterion, I'm uncertain as to what that means. I don't know what incoherence would be. But if coherence demands there is a regular

relationship between the risk factor and the disease process, that's what that means, then I may be mistaken there since I'm not an epidemiologist. We know and -- from personal experience, we have all got family members some of whom smoke and died at 95 and others smoked and they died at 45, and we don't know why it is that that happens.

We know people who smoke that have virtually no evidence of ischemic heart disease and we know people who smoke that have terrible ischemic heart disease. This is true for all the risk factors. So coherence criteria, assuming I've interpreted it correctly, fails.

I think what's happened here is they have established criteria which basically are setting themselves up for failure instead of taking risk factors as I interpret them to be, leads -- by "leads" I mean directions to pursue -- and then trying to identify the specific relationship of that lead to the disease in an experimental model.

So, I think I dealt with three of the four. I've forgotten what the fourth criterion was but it's probably --

Q. The strength of the association.

A. Well the strength of the association is actually

one of the crucial ones. I mean, we know, we talked yesterday at length that is an extremely -- if you take 3.0 risk times as the gold standard, and again I'm not an epidemiologist so I'm not going to claim that that's carved in stone, but if you accepted, say hypertension and stroke, then 1.7 may be wanting, and as I said many times yesterday, I'm not trying to pooh-pooh the important work that epidemiologists have done but I think again the concept of what is strong and what is weak has to be defined for me.

Q. Okay. Do you disagree with the surgeon general's conclusions regarding smoking as a cause of coronary heart disease?

MR. BORMAN: Object to the form of the question.

A. I'd have to once again read what their conclusions were. I think that the essence of the reports as I recollect them were reasonably stated that smoking is an important risk factor and any statements regarding cause I would view as being in the realm of public education and not in the realm of scientific thought.

MS. FLYNN PETERSON: Do you want to take a short break or keep going?

THE WITNESS: Sure, absolutely.

(Recess taken from 10:12 to 10:24 a.m.)

BY MS. FLYNN PETERSON:

Q. Have you been aware of, either through reading the report or the deposition testimony, of the opinions of Dr. Wunsch, the pathologist who is testifying in this case?

A. No, I'm not aware of his opinions.

Q. Were you aware he was involved in this case?

A. The name is familiar but I don't know of the specific opinion.

Q. His deposition was taken, I believe, within the last couple weeks. I don't know the exact date. I would just like to ask you whether you agree with some of the opinions that he's expressed in this case.

MR. BORMAN: Once again I will sort of interpose a continuing objection to any question about Dr. Wunsch's deposition unless Dr. Benditt has a chance to review it.

MS. FLYNN PETERSON: I understand he hasn't reviewed it, that was his testimony, and I will, as with other documents, show him what we are talking about.

MR. BORMAN: If I may just have a continuing objection so I don't have to interrupt.

MS. FLYNN PETERSON: Sure, you may. And that objection, I'll be happy to show any documents or deposition transcripts to Dr. Benditt as I refer to them.

MR. BORMAN: Thank you.

BY MS. FLYNN PETERSON:

Q. He expressed some opinions regarding the surgeon general, and it's always difficult when you start in the middle of something so let me -- the question that was asked to him --

MR. GINDER: Counsel, can you do page and line numbers of the transcript?

BY MS. FLYNN PETERSON:

Q. Page 96, the answer begins on line 20. It appears to be a point in the deposition where Dr. Wunsch is talking about the surgeon general and his answer is: The surgeon general is a political position. It is very often occupied by an individual who is not particularly distinguished in the medical profession. Rarely is it ever occupied by an individual who can be regarded as being in the forefront of the understanding of scientific issues.

Do you agree with that opinion expressed on page 96, beginning at lines 20 through 25?

A. In certain respects I agree with it. I probably

would not have been so forward as to say that this individual is not particularly distinguished in the medical profession. I would like to exclude that from my agreement. But I do believe that it is a political position and it may not necessarily be occupied by an individual with a lot of scientific expertise.

Q. Is that true for the surgeon generals who have held the position beginning in 1964 when the health consequences of smoking were first -- were first published?

MR. BORMAN: Hold on. I want to object simply to be clear there are many surgeon generals between then and now, so I'll object the question is overbroad.

A. My response would be that I don't know each of these individuals specifically and I would need to go through their CV's to give you a reasonable answer and not try to paint with a broad brush individuals who might be competent with others who might not be.

Q. With respect to any who might not be competent, does any specific surgeon general come to mind as you sit here now?

A. Well in terms of scientific competence, which is really the only issue that I think we were having a

problem with, I don't think that the immediate past surgeon general demonstrated those skills, and beyond that I would rather not comment because I think my knowledge of these individuals' specific talents is too vague to make a fair answer.

Q. Do you use ICD codes?

A. I don't personally use ICD codes, but ICD codes are an important part of our overall practice because they are the diagnostic codes upon which all billing is done.

Q. Are they reliable?

A. Depends on how you mean reliable. The reliability of the code as a depictor of the patient's illness is notoriously poor. The codes are largely used for billing purposes, not for medical descriptor purposes, and there are some important examples of where the kind of coding such as this has been used to look at medical issues and the outcomes have been quite spurious. Perhaps the most notorious of these was the example of the claim that there was an overplacement of pacemakers -- this was about a decade ago -- based on examinations of those kinds of diagnostic categories, and that proved to be really quite spurious. So I think it's a hazardous way to come to any medical description of patients, but it

turns out to be useful for billing purposes.
Q. How are they used? They refer to a certain medical diagnosis or condition; correct?
A. Correct. So essentially they are used by largely technicians or secretarial staff or basically people who are trained billing people that convert doctors' notes from medical records into these specific categories, and usually highlighting the category that's most appropriate for the most recent presentation of that patient, and may be or may not be including other underlying disease components that that person might have but might not have been specifically addressed at the last encounter.
Q. So in your experience, sometimes they are not as thorough, they don't include as many of the disease factors as they should?
A. Correct. And frankly, more and more we have ended up having to train specialists in how to use these codes, and of course different clinics have probably different degrees of expertise in coding charts.
Q. Do you have an opinion based on your experience as a cardiologist as to whether or not smoking is addictive?
A. I don't have a specific opinion because I really

don't know what the term "addiction" means in a general sense. I think that smoking is habit-forming and that that may be different from addiction. If we wanted to talk about addiction in the sense that there is a pharmacologic definition, which frankly I would have to review if you wanted to get into that, but elements of that include increasing use of the item as tolerance develops. Those kinds of definitions are part of the addiction process. I'm not sure that smoking qualifies in that regard, but as -- but as a habit, habituating, if you will, I think that might be a better characterization.

Q. You have told us through your testimony yesterday and today that it is your practice to recommend that if a patient of yours smokes that they discontinue smoking?

A. That's correct.

Q. Have you found, for those patients that you have made that recommendation, that all of your patients have been able to do so?

A. No.

Q. Have you had patients who have tried to do so and not been able to do so?

A. Yes.

Q. How frequently have you observed that in your

practice?
A. I would say that that's relatively common. Perhaps half the patients are able to either stop or markedly decrease their consumption and half are either unable to or don't want to listen to what I'm saying. I can't -- I don't know how to attribute the failure, whether it's due to the cigarette or whether it's due to the individual's desire.
Q. Do you believe that there are any benefits from cigarette smoking?
A. I can't think of any.
(Discussion off the record.)
MS. FLYNN PETERSON: Thank you, Dr. Benditt. I don't have any other questions.
THE WITNESS: Okay, thank you.
MR. BORMAN: I have no questions, but we would like Dr. Benditt to read and sign his deposition, please.
(Deposition concluded at approximately 10:37 o'clock a.m.)

C E R T I F I C A T E

I, David A. Campeau, hereby certify that I am qualified as a verbatim shorthand reporter; that I took in stenographic shorthand the foregoing deposition of DAVID G. BENDITT, M.D., at the time and place aforesaid; that the foregoing transcript, Volume II, consisting of pages 201 - 255, is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability; that the noticing party has been charged for the original transcript, and that ordering parties have been charged the same rate for such copies of the transcript.

Dated at Lino Lakes, Minnesota, this 16th day of September, 1997.

_____

SIGNATURE PAGE

I, DAVID G. BENDITT, M.D., the deponent, hereby certify that I have read the foregoing transcript, Volume II, consisting of pages 201 - 255, and that said transcript is a true and correct, full and complete transcription of my deposition, except per the attached corrections, if any.

(Please check one.)

____ Yes, changes were made per the attached (no.) _____ pages.

____ No changes were made.

_____

DAVID G. BENDITT, M.D.

Sworn and subscribed to before me this day of , 199__.

_____

Notary Public

My Commission expires: (DAC)